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BILL ANALYSIS

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Senate Bills 704 and 904 (as enacted) **PUBLIC ACTS 279 & 280 of 2014**
Sponsor: Senator Joe Hune
House Committee: Regulatory Reform
Senate Committee: Health Policy

Date Completed: 7-30-14

RATIONALE

Part 177 of the Public Health Code regulates the practices of pharmacies and pharmacists in this State. The Code currently regulates compounding pharmacies in the same manner as other pharmacies. In the last two years, there were several instances in which tainted drugs were found from compounding pharmacies. In it least one case, tainted drugs led to a nationwide outbreak of meningitis that resulted in 64 documented deaths, including 19 in Michigan. In light of these incidents, some suggested that the practice of compounding and the pharmacies that engage in the practice should be regulated to a greater extent.

CONTENT

Senate Bill 704 amends Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following:

- **Require an applicant for a pharmacy license for a pharmacy that will provide compounding services to submit verification of current accreditation through a national accrediting organization.**
- **Create an application process and standards for a pharmacist or pharmacy compounding pharmaceuticals for a prescriber, health facility, or agency.**
- **Require a pharmacist to maintain records of compound sterile pharmaceuticals.**
- **Require a pharmacy, manufacturer, or wholesale distributor to designate a licensed pharmacist as the pharmacist in charge (PIC), and establish the duties of a PIC.**
- **Require certain applicants for new pharmacies, manufacturers, or wholesale distributors to undergo a criminal history check.**
- **Prescribe criminal penalties for violations of some of the above provisions.**

The bill also amends Part 161 (General Provisions) of the Code to provide for the summary suspension of a pharmacy license if the Department of Licensing and Regulatory Affairs receives a notice of imminent risk to public health or safety from the United States Food and Drug Administration (FDA) or the Centers for Disease Control and Prevention (CDC).

Senate Bill 904 amends the Code of Criminal Procedure to include in the sentencing guidelines the felonies created by Senate Bill 704, as well as the offense of purchasing or possessing ephedrine or pseudoephedrine knowing that it is to be used for making methamphetamine.

Both bills will take effect on September 30, 2014. Senate Bill 904 was tie-barred to Senate Bill 704 and House Bill 5363 (Public Act 216 of 2014). (House Bill 5363 amends the Public Health Code, effective January 1, 2015, to prohibit a person from purchasing or possessing any amount of ephedrine or pseudoephedrine knowing or having reason to know that it is to be used to

manufacture methamphetamine. The offense will be a felony punishable by imprisonment for up to five years and/or a maximum fine of $5,000.)

Senate Bill 704

Regulation of Compounding Pharmacies

Under Section 17748a, added by the bill, an applicant for a new pharmacy license for a pharmacy that will provide compounding services for sterile pharmaceuticals must submit verification of current accreditation through an approved national accrediting organization or verify that the pharmacy is in the accreditation process. The Department of Licensing and Regulatory Affairs (LARA) may not issue a license to the pharmacy if it is not accredited, unless the applicant demonstrates compliance with USP standards.

(The bill defines "compounding" as "the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist" upon the receipt of a prescription for a specific patient or a prescriber's medical order for treatment of patients within the course of the prescriber's practice, or in anticipation of receiving a prescription or medical order based on routine, regularly observed prescription or medical order practices, or for research, teaching, or chemical analysis purposes. Compounding does not include the compounding of a drug product that is essentially a copy of a commercially available product, or the mixing, reconstitution, or similar act performed according to directions on the label provided by the manufacturer of a commercially available product, or the compounding of allergenic extracts or biological products. "Sterile pharmaceutical" means "a dosage form of a drug that is essentially free from living microbes and chemical or physical contamination to the point at which it poses no present risk to the patient, in accordance with USP standards". "USP standards" means "the pharmacopeial standards for drug substances, dosage forms, and compounded preparations based on designated levels of risk as published in the official compendium".)

Within one year after the bill's effective date, a pharmacy that is licensed on that date and provides compounding services for sterile pharmaceuticals must be accredited by a national accrediting organization approved by the Michigan Board of Pharmacy, be verified by the Board as being in the accreditation process, or be in compliance with USP standards in a manner determined by the Board.

A pharmacy that provides compounding services for sterile pharmaceuticals must submit with its license renewal application verification of accreditation or compliance with USP standards.

A person that provides services consistent with an outsourcing facility is required to comply with FDA requirements applicable to compounding services for sterile pharmaceuticals.

A pharmacy must notify LARA of a complaint filed in another state for a violation of that state's pharmacy laws, a Federal investigation regarding violations of Federal law, or an investigation by any agency into violations of accrediting standards regarding compounding activities, within 30 days of knowledge of the complaint or investigation.

Section 17748a also requires a pharmacist to maintain a record of compound sterile pharmaceuticals in the same manner and for the same retention period as required for other prescription records, except for distribution within a hospital or another health care entity under common control when regulated by Federal law. The record must include the following information: a) the name, strength, quantity, and dosage form of the compounded pharmaceutical, b) the formula to compound that includes mixing instructions, all ingredients and their quantities, and any other information needed to prepare the compounded pharmaceutical, c) the prescription number or assigned internal identification number, d) the preparation date, e) the manufacturer and lot number of each ingredient, f) the expiration or beyond-use date, g) the name of the person who prepared the pharmaceutical, and h) the name of the pharmacist who approved the compounded pharmaceutical.

A pharmacist is prohibited from offering excess compounded pharmaceuticals to other pharmacies for sale, and a compounding pharmacy is prohibited from distributing samples of compounded pharmaceuticals to a health professional, but may advertise or promote the fact that it offers compounding services.

A pharmacist may compound a nonsterile or sterile pharmaceutical not commercially available if there is a health professional-patient relationship and a valid prescription, or in anticipation of receiving a prescription based on routine, regularly observed prescription practices.

A person may compound and manufacture drug products or allow the compounding and manufacturing of drug products at the same location.

In consultation with the Board, LARA may promulgate rules regarding conditions, good compounding practices, and facilities for the compounding of sterile and nonsterile pharmaceuticals.

Compounding Pharmaceuticals for a Prescriber, Facility, or Agency

Under Section 17748b, added by the bill, a pharmacist or pharmacy is prohibited from compounding nonsterile or sterile pharmaceuticals for a prescriber, health facility, or agency licensed under Article 17 to administer to the prescriber's, facility's, or agency's patients without a prescription, unless the pharmaceutical compounded by the pharmacist or pharmacy complies with the most recent guidance on pharmacy compounding of human drug products under Federal law. (Article 17 governs facilities and agencies.) The Department may authorize this activity for limited quantities, however, upon application by a pharmacist or compounding pharmacy. Authorization may not be granted if the pharmacist or pharmacy is under investigation, in the process of being disciplined, or in disciplinary status.

The Department must prescribe the form of the application, which must include all of the following information: a) the name and license number of the pharmacist or pharmacy requesting authorization to compound, b) the name of the specific prescriber, health facility, or agency requesting compounded pharmaceuticals and an affidavit from the prescriber or designated agent of the facility or agency attesting to the need and that the compounded pharmaceuticals are only for patients located in Michigan or immediately adjacent states, c) the pharmaceuticals to be compounded and the reason for compounding, d) the anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound, and e) the conditions of operation, including practices consistent with USP standards and requirements for sterility testing.

A pharmacist or compounding pharmacy authorized to compound nonsterile or sterile pharmaceuticals for a prescriber, facility, or agency must maintain accurate and complete monthly records of requests from and pharmaceuticals compounded for each prescriber, facility, or agency, and provide the records to LARA as specified in rules or upon request.

If a pharmacy or pharmacist becomes aware of an adverse event associated with a compounded pharmaceutical, the pharmacy or pharmacist must report the event to the Department within 10 days after becoming aware of the event. An adverse event does not include an isolated allergic reaction to a substance included in the compound if the allergic reaction is treated and relieved with standard protocol.

The authorization will last for two years, consistent with the two-year license cycle of the pharmacy. The Department may inspect the facility where the compounding occurs without prior notice to the pharmacist or the pharmacy. The Department may immediately revoke the authorization if there is a confirmed deviation or violation of the compounding process, or if an adverse event directly related to sterility or integrity of the product and associated with a compounded sterile or nonsterile pharmaceutical is detected. If the health, safety, and welfare of the public are not in immediate danger, LARA must provide at least 30 days' notice of the revocation.

A prescriber, facility, or agency that obtains compounded pharmaceuticals under Section 17748b may not redistribute or sell the compounded pharmaceuticals to a patient, prescriber, facility, or agency.

The Department is required to post and maintain on its website a list of pharmacies and pharmacists authorized to compound pharmaceuticals under Section 17748b.

Compounding Commercially Available Pharmaceuticals

The bill prohibits a pharmacist from compounding a commercially available pharmaceutical, except for pharmaceuticals on the Michigan Pharmaceutical Product List maintained by the Department of Community Health. This prohibition does not apply if, in the judgment of the prescriber, the commercially available pharmaceutical is modified to produce a significant difference between the compounded pharmaceutical for the patient and the commercially available pharmaceutical, and the commercially available pharmaceutical is not available in normal distribution channels in a timely matter to meet the patient's needs. A pharmacist who compounds a commercially available pharmaceutical must maintain documentation of the reason for compounding.

Summary Suspensions

The Public Health Code allows, and in some cases, requires, the Department to summarily suspend a license or registration if the public health, safety, or welfare requires immediate action. The bill allows LARA to summarily suspend a pharmacy license if the Department receives a notice from the FDA or CDC that there is an imminent risk to the public health, safety, or welfare, and emergency action in accordance with the Administrative Procedures Act is appropriate. A summary suspension under these circumstances will remain in effect for the duration of the emergency situation. The Department is not required to conduct an investigation or consult with the Board of Pharmacy to take emergency action.

If a pharmacy's license is summarily suspended, LARA must report the name and address of the suspended pharmacy license to the Department of Community Health, the Department of Insurance and Financial Services, the State and Federal agencies responsible for administering Federal health care programs, and the appropriate professional association.

Licensure of Pharmacies; Pharmacist in Charge

The Code requires a pharmacy, drug manufacturer, or wholesale distributor doing business in Michigan to obtain a license. The license is renewable every two years. The bill requires a person that provides compounding services to be licensed as a pharmacy or manufacturer, and an outsourcing facility to be licensed as a pharmacy.

The Code also requires a pharmacy, manufacturer, or wholesale distributor to designate an individual to serve as the licensee for the entity. The designated individual has the responsibility of ensuring the entity's complies with Part 177.

The bill, instead, requires a pharmacy to designate a pharmacist licensed in Michigan as the pharmacist in charge for the pharmacy. A manufacturer or distributor must designate a pharmacist licensed in Michigan or another state as the PIC. The PIC, and the pharmacy, manufacturer, or wholesale distributor are jointly responsible for ensuring compliance with Part 177 and rules promulgated under it.

A pharmacist may be designated as the PIC for more than one pharmacy. Such a pharmacist is required to work an average of at least eight hours per week at each pharmacy for which he or she is the PIC.

A Pharmacist in charge must supervise the practice of pharmacy at each pharmacy in which he or she is designated the PIC, and is required to do at least all of the following:

-- Supervise all activities of pharmacy employees related to the practice of pharmacy, including purchasing, storing, compounding, repackaging, dispensing, and distributing all drugs and devices.
-- Enforce and oversee employee policies and procedures for the procurement, storage, compounding, and dispensing of drugs and the communication of information to patients in relation to drug therapy.
-- Establish and supervise the method and manner for the storage and safekeeping of pharmaceuticals.
-- Establish and supervise the record-keeping system for the purchase, sale, possession, storage, and safekeeping of drugs and devices.
-- Establish policies and procedures for individuals within the pharmacy who are delegated tasks by the PIC.

A pharmacy, manufacturer, or wholesale distributor must report to the Department a change in ownership, management, location, or designated PIC within 30 days of the change.

An applicant for a new pharmacy, manufacturer, or wholesale distributor license who is not a health professional licensed or otherwise authorized to engage in a health profession or who is a health professional but was licensed or authorized to engage in a health profession before October 1, 2008, is required to submit fingerprints in the same manner as required under Section 16174 for a criminal history check. (Section 16174 requires an applicant for a license to forward his or her fingerprints to the Department of State Police for a criminal history check with a request that the fingerprints be forwarded to the Federal Bureau of Investigation for a national criminal history check.) The Department, the Board, and the Department of State Police also must comply with Section 16174. This requirement for a criminal history check does not apply if a check that meets the requirements of Section 16174 has been obtained for the applicant within the two years before the date of the application. To qualify for this exception, the applicant must submit proof of the previous criminal history check with the application for a new license. If LARA or the Board determines that the criminal history check does not meet the requirements of Section 16174, or was not obtained within the prescribed time frame, the applicant must undergo a new criminal history check.

Criminal Penalties

A person who violates Section 17748a or 17748b will be guilty of a misdemeanor. If a person knowingly or willfully violates either section, or falsifies prescriptions in order to compound a pharmaceutical in bulk, the person will be guilty of a felony punishable by up to two years in prison or a maximum fine of $1,000, or both.

If a person knowingly or willfully violates Section 17748a or 17748b, or falsifies prescriptions in order to compound a pharmaceutical in bulk, and the violation results in personal injury, the person will be guilty of a felony punishable by up to four years in prison or a fine of up to $4,000, or both. If the violation results in the serious impairment of a body function, the penalty is up to five years in prison or a fine of up to $5,000, or both. If the violation results in death, the penalty is up to 15 years in prison or a maximum fine of $20,000, or both.

"Serious impairment of a body function" means that term as defined in Section 58c of the Michigan Vehicle Code. ("Serious impairment of a body function" includes but is not limited to, one or more of the following: a) loss of a limb or loss of use of a limb, b) loss of a foot, hand, finger, or thumb or loss of use of a foot, hand, finger, or thumb, c) loss of an eye or ear or loss of use of an eye or ear, d) loss or substantial impairment of a bodily function, e) serious visible disfigurement, f) a comatose state that lasts for more than three days, g) measurable brain or mental impairment, h) a skull fracture or other serious bone fracture, i) subdural hemorrhage or subdural hematoma, or j) loss of an organ.)

The bill authorizes the Attorney General or a local prosecutor to prosecute the criminal charges described above.

Senate Bill 904

The bill includes the felonies proposed by Senate Bill 704 in the sentencing guidelines as follows:

-- A compounding pharmacy violation is a Class G crime against a person with a statutory maximum of two years.
-- A compounding pharmacy violation resulting in personal injury is a Class F crime against a person with a statutory maximum of four years.
-- A compounding pharmacy violation resulting in serious impairment of a body function is a Class E crime against a person with a statutory maximum of five years.
-- A compounding pharmacy violation resulting in death is a Class C crime against a person with a statutory maximum of 15 years.

The bill also includes the felony of purchasing or possessing ephedrine or pseudoephedrine knowing or having reason to know that it is to be used to manufacture methamphetamine as a Class E controlled substance offense with a statutory maximum of five years (as enacted by House Bill 5363).

MCL 333.16233 et al. (S.B. 704)
777.13m (S.B. 904)

BACKGROUND

Compounding, Generally

Compounding is a practice in which a pharmacist or physician combines or alters the ingredients of a drug to "tailor" a new drug for a patient.[1] Historically, drugs were frequently compounded. With the advent of mass-produced pharmaceuticals, this practice is no longer as common as it once was, but the practice is still used in certain circumstances. Compounding is typically done for patients with specific needs.[2] For example, if a patient is allergic to a dye found in a commercially available drug, a pharmacist could compound the same drug without the dye. Another example where compounding is useful is when a drug is available in one form (e.g., a pill), but a patient prefers or requires another form (e.g., liquid form), a pharmacist could compound the alternative form. The practice of compounding allows a physician to work with a pharmacist to develop a drug to suit a patient's particular needs.

Regulation of Compounded Pharmaceuticals

The United States Food and Drug Administration (FDA) has the authority to regulate drugs, vaccines, medical devices, and other biological products meant for human use. Most of these items are regulated under the Federal Food, Drug, and Cosmetic Act (FDCA). However, for the majority of the time after passage of the FDCA, the FDA left the regulation of compounded drugs to the states. For example, compounded formulations are not FDA-approved. This is because the FDA regulatory approval process is meant for mass-produced pharmaceuticals. The approval process for pharmaceuticals can be expensive and time-consuming. Compounded pharmaceuticals are typically used soon after compounding (e.g., at a hospital), are usually for individualized treatments, and are less likely to be transferred though interstate commerce than mass-produced pharmaceuticals. Thus, requiring FDA approval for each formulation is thought to be unnecessary.

For those reasons, most aspects of compounding have been left to the states to regulate. The intrastate regulation of compounding pharmacies is usually conducted by a state's Board of

[1] "What is Compounding?", Professional Compounding Centers of America, retrieved 7-17-2014 at: http://www.pccarx.com/what-is-compounding/what-is-compounding.
[2] *Id*.

Pharmacy.[3] In Michigan, the Board of Pharmacy has duties under Parts 161 and 177 of the Public Health Code. Among other things, the Board is required to do the following:

-- Regulate, control, and inspect the character and standards of pharmacy practice and drugs manufactured, distributed, prescribed, and administered in this State, procure samples, and limit or prevent the sale of drugs that do not comply with the relevant Code provisions.
-- Prescribe minimum criteria for the use of professional and technical equipment in reference to the compounding and dispensing of drugs.
-- Grant pharmacy licenses for each place of practice of a dispensing prescriber who meets requirements for drug control licensing.
-- Grant licenses to manufacturers and wholesaler distributors of prescription drugs.
-- Discipline licensees who have adversely affected the public's health, safety, and welfare.

Notwithstanding the states' role in regulating the compounding of pharmaceuticals, the Federal government has tried to regulate the practice. In 1992, the FDA issued the Compliance Policy Guide. This was done to alleviate concerns that pharmacists were manufacturing drugs and selling them under the pretense of compounding.[4] The Guide explained that retail pharmacies that practiced compounding were not exempt from the FDCA's new drug adulteration or misbranding provisions. The Guide specified that compounding was to be limited to circumstances in which there was a valid prescription; or, before the receipt of a valid prescription, there was a documented history of receiving valid prescriptions in the context of an established medical professional relationship, in which case a pharmacist could compound limited quantities of a drug.[5] The Guide also specified that compounding was acceptable, so long as the pharmacy did not engage in activities that raised concerns normally associated with a manufacturer. The guide cited nine examples of such activities.[6]

In 1997, Congress codified portions of the Guide by passing the Food and Drug Administration Modernization Act (FDAMA), which amended the FDCA. Of relevance to compounding pharmacies was Section 127a (codified at 21 U.S.C. § 353a). The FDAMA exempted compounded drugs from many of the FDCA's drug approval requirements, provided certain conditions are met. Section 127a of the FDAMA specified that compounded drugs had to: a) be compounded by a licensed pharmacist or physician in response to a valid prescription, or in response to a history of receipt of a valid prescription within an established relationship between patient, pharmacist, and physician, b) be made from approved ingredients that met manufacturing and safety standards, c) not be compounded regularly, or in inordinate amounts, if the drug that is essentially a copy of commercially available drug, and d) not be one identified by the FDA as being a drug product that presents difficulties for compounding safely or effectively.[7] Section 127a prohibited entities from distributing compounded drugs out of a state in certain quantities unless the state had entered into a memorandum of understanding with the FDA. Furthermore, Section 127a required prescriptions of compounded drugs to be unsolicited, and banned a pharmacy, licensed pharmacist, or licensed physician compounding the drug from advertising or promoting the compounding of any particular drug, class of drug, or type of drug.[8]

Within days of taking effect, Section 127a was challenged in court because of the advertising provision. On appeal, the United States Supreme Court held that the provision pertaining to promotion and advertising was unconstitutional because it amounted to an impermissible restriction on commercial speech.[9] In light of this decision, the FDA reissued the Compliance

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[3] "Compounding and the FDA: Questions and Answers", U.S. Food and Drug Administration, retrieved 7-16-2014 at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm.

[4] *Pharmacy Compounding*, Compliance Policy Guide, § 7132.16 (renumbered 460.200), 3-1992.

[5] See *Thompson v. Western States Medical Center*, 535 U.S. 357, 362-63 (2002).

[6] *Id*. at 363.

[7] 21 U.S.C. § 353a (1998).

[8] 21 U.S.C. § 353a(c) (1998).

[9] *Western States Medical Center*, 535 U.S. 357, at 360. When a portion of a law is found unconstitutional, courts are faced with the issue of whether the unconstitutional provision can be severed from the rest of law, which allows the remaining provisions of the law to be enforced. In this

Policy Guide for Pharmacy Compounding, which essentially reiterated the same points as the previous Guide without the advertising and promotion provision.[10]

The New England Compounding Center Meningitis Outbreak & Subsequent Action

Between May and October 2012, an outbreak of rare fungal meningitis was reported throughout the United States. Eventually, the CDC traced the outbreak to contaminated epidural steroid injections packaged and marketed by the New England Compounding Center (NECC), a compounding facility based in Framingham, Massachusetts. The steroids were contaminated with various fungi, including *Exserohilum rostratum* and *Aspergillus fumigatus*.[11]

Due to the rarity of fungal meningitis and the unusual nature of the infectious agents involved, clinicians were unaccustomed to treating the problem. Age and poor health contributed, in part, to the condition of victims who contracted the infection.[12] Individuals who were treated in and released from a hospital occasionally returned to the hospital for recurring fungal infections or sequelae.[13] In addition to meningitis, infected individuals suffered from debilitating pain, strokes, and a variety of other symptoms and illnesses. By late October 2013, 751 total cases resulting in 64 deaths were documented nationwide. Among the states hardest hit were Indiana, Michigan, New Jersey, Tennessee, and Virginia.[14] The CDC estimated that nearly 14,000 people were injected with steroids from the three lots that contained the fungi, but were not infected.

On October 12, 2012, Michigan's Attorney General filed an Order of Complaint and Summary Suspension with LARA to suspend NECC's license to operate in this State.[15] On December 12, the Michigan Board of Pharmacy agreed to accept the voluntary surrender of NECC's Michigan licenses.[16]

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case, the Ninth Circuit held that the advertising and promotion provision was not severable from the rest of Section 127a because the legislative history of the FDAMA showed that Congress intended to exempt compounding from regulation under the FDCA in exchange for the prohibition on advertising compounded drugs. The matter was not included in the petition for certiorari (appeal) to the U.S. Supreme Court and was not reviewed by the Supreme Court, which left the Ninth Circuit decision intact and the entirety of Section 127a invalid.

[10] Kevin Outterson, "Regulating Compounding Pharmacies after NECC", *New England Journal of Medicine*, Vol. 367, p. 1970, 11-22-2012; See *Pharmacy Compounding*, Compliance Policy Guide, § 460.200, 5-2002.

[11] "Multiple Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Phamacy – United States, 2012", *Morbidity and Mortality Weekly Report*, 10-19-2012, retrieved 6-25-2014 at: http://www.cdc.gov/mmwr/preview /mmwrhtml/mm6141a4.htm?s_cid=mm6141a4_w. Both of these fungi are ubiquitous and seldom cause health complication. In the case of *A. fumigatus*, documented health problems have been observed in immunocompromised individuals, and rarely, as the causal agent in meningitis cases. *E. rostratum* is a ubiquitous black mold typically found in soil or plants. It has been documented in human infections of the cornea and in more severe infections in immunocompromised individuals. "Fungal Diseases", U.S. Centers for Disease Control and Prevention, retrieved 6-25-2014 at: http://www.cdc.gov/fungal/diseases/index.html.

[12] See n. 11, "Multiple Outbreak of Fungal infection". Based on preliminary information on 70 patients, the median age of those patients was 68 years old. Many of these patients had comorbidities (the presence of two or more chronic diseases or conditions) that exacerbated their condition.

[13] A sequela is a secondary condition that results from a disease.

[14] "Multistate Outbreak of Fungal Meningitis and Other Infections-Case Count", U.S. Centers for Disease Control and Prevention, retrieved 6-19-2014 at: http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html. Michigan accounted for 264 total cases and 19 deaths.

[15] "Snyder, Schuette Move To Spend License For Company Linked To Meningitis Outbreak", Press Release 10-12-2012, State of Michigan Attorney General.

[16] "In Wake of NECC Tragedy, Senate Unanimously Approves Compounding Pharmacy Legislation", Press Release 5-13-2014, State of Michigan Attorney General.

By December 2012, over 400 lawsuits had been filed against the NECC, and the company filed for Chapter 11 bankruptcy.[17] In July 2014, the bankruptcy court approved a $100 settlement; a master plan detailing how creditors and victims will be paid is expected in August.[18]

In response to the NECC outbreak and several other incidents throughout the United States, Congress passed the Drug Quality and Security Act (DQSA). It was signed into law in November 2013. Title I of the DQSA, called the Compounding Quality Act, relates specifically to drug compounding and created a new section of law that pertains to outsourcing facilities.[19] Section 503b requires facilities that elect to register as outsourcing facilities to comply with certain requirements in order to be exempt from the drug application and manufacturer, repackager, wholesale distributor, and dispenser transaction requirements that are mandatory for mass-produced pharmaceuticals.[20] Also, Section 106 of Compounding Quality Act severed the provision prohibiting the advertisement or promotion of the compounding of pharmaceuticals, rendering Section 503a (21 U.S.C. § 353a) enforceable.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Until recently, Michigan was one of the states in the United States that had not adopted compounding safety legislation. The bills are needed to prevent incidents resulting from improper compounding of pharmaceuticals. The NECC outbreak killed 19 people in Michigan (64 nationwide), and many more are suffering as a result of the tainted steroids they received from the NECC. A number of these deaths were preventable, as the contamination was primarily from a failure to follow standard procedures and regulations concerning the compounding of pharmaceuticals and their distribution.[21] While many victims survived, some continue to struggle with pain, short-term memory loss, loss of mobility, and expensive medical bills from past and ongoing treatment. Some victims have lost their homes as a result of medical bills and loss of income because of an inability to work.[22]

The outbreak because of tainted drugs from the NECC was not the only incident that occurred. In 2013, a South Lyon pharmacy ceased operations after tainted dextrose injections were distributed to various hospitals in Michigan.[23] The pharmacy was alleged to have acted as a drug manufacturer by distributing large amounts of medication to hospitals, although it was licensed

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[17] JoNel Aleccia, "Pharmacy tied to fungal meningitis outbreak files for bankruptcy", *NBC News*, 12-22-2012, retrieved 7-16-2014 at: http://vitals.nbcnews.com/_news/2012/12/21/16074297-pharmacy-tied-to-fungal-meningitis-outbreak-files-for-bankruptcy.

[18] Jessica Bartlett, "Judge affirms $100 million settlement with New England Compounding Center", *Boston Business Journal*, updated 7-15-2014, retrieved 7-16-2014 at: http://www.bizjournals.com/boston/blog/health-care/2014/07/judge-affirms-100-million-settlement-with-new.html?page=all.

[19] Codified as 21 U.S.C. § 503b. An "outsourcing facility" is a facility at one geographic location or address that: i) is engaged in the compounding of sterile drugs; ii) has elected to register as an outsourcing facility; and iii) complies with all of the requirements of Section 353b. An outsourcing facility is not required to be a licensed pharmacy and has the option to obtain prescriptions for identified individual patients. 22 U.S.C. § 353b(d)(4)(A)-(C).

[20] 21 U.S.C. § 353b(a). See "FDA Implementation of the Compounding Quality Act", http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm, for a more detailed explanation of these requirements.

[21] See, e.g., Abby Goodnough, "Sterilty Found Lacking at Drug Site in Outbreak", *New York Times*, 10-23-2012, retrieved 6-25-2014 at: http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all ; Denise Grady, et al., "Scant Oversight of Drug Maker in Fatal Meningitis Outbreak", *New York Times*, 10-6-2012, retrieved 6-25-2014 at: http://www.nytimes.com/2012/10/07/us/scant-drug-maker-oversight-in-meningitis-outbreak.html?pagewanted=all&_r=0. See also Outterson, n. 10.

[22] Oral testimony, Senate Health Policy Committee, 4-24-2014.

[23] See n. 16

only to fill individual prescriptions for patients. While no reports of other illnesses have been received to date, it is another compelling example of the need to regulate these pharmacies more strictly.

The requirements put forth by these bills should prevent incidents similar to the NECC meningitis outbreak, by allowing LARA to summarily suspend licenses in the event of a public safety emergency. The bills will require accurate record-keeping, which will help prevent accidents and save lives by enabling pharmacists to check their work and allowing regulators to ensure that compounding pharmacies are following the law. The bills will require pharmacies to submit to inspections, which will help prevent the sort of contamination that led to the NECC outbreak. The criminal penalties will assist the Attorney General and other units in prosecuting these cases.

Opposing Argument

Some businesses provide mail-order pharmacy services to Michigan residents from outside of the State. To do business in this State, they are licensed under Michigan law. The current law requires that a pharmacist having personal charge of a pharmacy be licensed in the state where he or she practices in and to comply with Michigan laws and regulations. Senate Bill 704 will require the PIC of an out-of-State pharmacy to be licensed in Michigan. Since these pharmacies are already subject to Michigan laws, regulations, and penalties, this mandate will impose burdens without any real benefit. The bill puts Michigan out of conformity with other states and the national trend of removing these requirements.

Legislative Analyst: Jeff Mann

FISCAL IMPACT

The bills will have no fiscal impact on the Department of Licensing and Regulatory Affairs.

The bills create new misdemeanor and felony penalties. The sentences for felony convictions will cost the State approximately $35,000 per prisoner per year. The penalties associated with misdemeanor convictions will have a financial cost to local jails and court systems to administer the sentences. If any associated fine revenue is collected from convictions under the new penalties, the revenue will be directed to local public libraries.

Fiscal Analyst: John Maxwell
Josh Sefton